

REMARKS

The withdrawal of claims 8-21 and 23 from consideration and the statement that upon allowance of product claims, rejoinder of process of making claims and method of use claims commensurate in scope with the allowed product claims will be permitted, are acknowledged. Applicants respectfully request retention of the process of making and method of use claims in the application pending allowance of the product claims.

The indication of allowable subject matter in product claims 3, 5 and 6 is also acknowledged. Applicants have not, however, deemed it necessary to re-write these claims in independent form, because they are believed allowable with the parent claims as discussed hereinafter.

Applicants hereby respectfully traverse the attempted withdrawal of portions of claims 1-7 and 22 and the related objection to claims 1, 7 and 22 for allegedly containing non-elected subject matter. These actions are improper because they contravene the applicants' statutory right to claim what **they** regard as their invention. As was succinctly stated by the Court of Customs and Patent Appeals in *In re Weber*, 580 F.2d 455, 198 U.S.P.Q. 328, 331 (CCPA 1978):

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112. We have decided in the past that §112, second paragraph, which says in part "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it. *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

It is not a prerogative of the Patent and Trademark Office to define the generic scope of applicants' invention. That is, by statute, exclusively the right of the applicants. See also MPEP § 803.02, ¶2. As stated in the MPEP, it is improper for the office to refuse to examine that which applicants regard as their invention. Note that unity of invention is present in this case because the claimed compounds all (1) share the common utility of analgesic activity, and (2) share the substantial structural features of formula I which are essential to that utility. Accordingly, reconsideration and withdrawal of the attempted restriction of a portion of claims 1-7 and 22 and objection to claims 1, 7 and 22 are respectfully requested.

The rejection of claims 1, 7 and 22 under 35 U.S.C. § 102(b) over Montgomery et al., U.S. 4,473,709 or Wu et al., WO 98/22433 or Misiorny et al., Acta Pharm Suec. 14:105-112 (1977) is also respectfully traversed.

Insofar as the rejection is based on Montgomery et al., it is fatally flawed for two reasons. First, the rejection is based on the assertion that claim 1

discloses biphenyl-2-ylmethyldimethylamine hydrochloride, but this assertion is incorrect. Claim 1 of the Montgomery et al. '709 patent teaches N,N,N-trimethyl-[1,1'-biphenyl]-2-methanaminium salts. Note that in the formula in claim 1, there are three methyl groups plus a biphenylmethylene group attached to the nitrogen atom. These compounds are distinct from simple hydrochloride salts. In the second place, the compound biphenyl-2-ylmethyldimethylamine is specifically excluded by the proviso in claims 1 and 22, where it is the second compound listed in each case. As for claim 7, biphenyl-2-ylmethyldimethylamine hydrochloride has been excluded from the scope of the claim.

The disclosure of Wu et al. is directed to a class of dipeptide derivatives which are clearly distinct from the presently claimed analgesic compounds. The rejection, however, points to the chemical abstract of Wu et al. which indicates that the compound [1,1'-biphenyl]-2-methanamine is disclosed as a reactant or reagent in Wu et al. This compound, however, is not a "dialkylaminoalkyl-" compound as now claimed by applicants. See, e.g., amended claims 1 and 22 which require that R⁴ and R⁵ be C1-6 alkyl groups.

The Misiorny et al. article discloses, among other compounds, the compound 2, 3-dimethoxy-2'-dimethylaminomethylbiphenyl. However, this compound is excluded from the scope of the amended claims by the requirement in amended claims 1 and 22 that if R¹, R² or R³ is an alkoxy group, it must be in the 3' or 5' position. Support for this recitation is found in the specific examples

Serial No. 10/071,229

listed in claim 7 (See, e.g., the 1st, 10th, 21st, 22nd, 23rd, 33rd, 34th, 39th and 40th compounds listed in original claim 7).

Accordingly, the rejection of claims 1, 7 and 22 under 35 U.S.C. § 102(b) over Montgomery et al., WU et al. or Misiorny et al. should be withdrawn.

Finally, the rejection of claims 1, 2, 4, 5, 7 and 22 under 35 U.S.C. § 103(a) over Montgomery et al. or Wu et al. or Misiorny et al. is also respectfully traversed. The inclusion of claim 5 in this rejection is believed to have been an inadvertent clerical error, since claim 5 is *twice* indicated elsewhere to define allowable subject matter.

The obviousness rejection is based on the notion that it would somehow have been obvious to modify the distinctly different compounds of Montgomery et al., Wu et al. or Misiorny et al. in order to derive the presently claimed compounds. Applicants emphatically disagree. None of the references of record teaches, discloses or suggests such modifications in any way. There is nothing in any reference of record which provides guidance to a person skilled in the art as to what portions of the reference molecules should be modified, what modifications should be made, or how the necessary modification should be made. Thus, there is absolutely no impetus which would lead a person of ordinary skill to make the modifications which would be needed, or any teaching which would enable him to know what types of modifications should be made, where they should be made, or how to make them. Obviousness can only be established by modifying prior art compounds to produce the claimed invention when there is some teaching, suggestion or motivation to do so in the prior art.

See *In re Jones*, 958 F.2d 347, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992). There is no such teaching, suggestion or motivation in this case, and thus, the record fails to make out a proper, *prima facie* case of obviousness.

The Office Action attempts to support the obviousness rejection by asserting that “it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results.” Applicants respectfully disagree. Neither *In re Wood* or *In re Lohr*, cited in the Office Action as supporting this proposition, establishes any such general rule. Indeed, *In re Lohr* expressly holds that such supposed general rules are improper and states instead that each case must be considered on its individual facts:

While this court stated in *In re Victor Mills*, 47 CCPA 1185, 281 F.2d 218, 126 U.S.P.Q. 513, with respect to the *Henze* case, that statements applicable to particular fact situations should not be frozen into “legal rules of general application,” we do reaffirm the statement in *Henze* that “whether invention exist over prior art isomers and homologues is a question to be decided in each case. *In re Lohr*, 137 U.S.P.Q. 548, 551 (CCPA 1963).

Thus, a proper *prima facie* case of obviousness is only made out when the prior art provides some suggestion or motivation to make the claimed combination, and each case must be decided on its individual facts, and not on the basis of so-called “general rules of law.”

The motivation to make the proposed modifications is especially lacking in this case because there is either no reasonable expectation of similar properties or the prior art compounds either have no utility or are useful only as intermediates.

In the case of Montgomery et al., the prior art compounds are disclosed as pesticides, which clearly would not be suitable for human ingestion. In contrast, the presently claimed compounds are pharmaceutically useful as analgesics. There is no similar utility which could give rise to a presumption of obviousness.

With regard to Wu et al., the reference compound is disclosed only as an intermediate reactant, and one of ordinary skill in the art would not have been motivated to investigate such reactants with an expectation of arriving at the claimed analgesics. See *In re Lahu*, 747 F.2d 703, 223 U.S.P.Q. 1257 (Fed. Cir. 1984).

As for Misiorny et al., the article is a report of an investigation to learn whether certain compounds would have the apomorphine-like property of stimulating dopaminergic receptors. Pointedly, Misiorny et al. conclude on page 107 that all of the investigated compounds “did not show any appreciable activities.” See also table one on page 108 of Misiorny et al. Consequently, the Misiorny et al. compounds are not disclosed as having any specific or significant utility, and there is no motivation for one of ordinary skill in the art to attempt to make modifications of such compounds, because there can be no expectation that such modified compounds would have any utility either. See *In re Stemniski*, 444 F.2d 581, 170 U.S.P.Q. 343 (CCPA 1971).

Accordingly, the cited references clearly fail to make out a proper *prima facie* case of obviousness, and reconsideration and withdrawal of the rejection are respectfully requested.


Serial No. 10/071,229

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #148/50899).

Respectfully submitted,

June 18, 2003



J. D. Evans
Registration No. 26,269

CROWELL & MORING, LLP
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844